



OCT 24 2005

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Mr. Daniel Zwiren
President
Prometheon Labs LLC
750 Lexington Avenue
New York, New York 10022

Dear Mr. Zwiren:

This is in response to your letter of September 2, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Prometheon Labs LLC is making the following claims, among others, for the product **Avatar 8™ with AC-11®**:

- “Anti-inflammatory, helps prevent release of pro-inflammatory agents”
- “Helps relieve pain due to inflammation caused by injury or chronic condition”
- “Helps speed recovery from injury....”
- “Help reduce swelling and immobilization”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, namely inflammatory diseases and injuries. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Page 2 - Mr. Daniel Zwiren

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to be 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

PROMETHEON LABS LLC ~ 750 Lexington Avenue, New York, NY 10022

September 2, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS 800)
Food and Drug Administration
200 C Street, S.W.
Washington D.C. 20204

OCT - 3

Sir/Madam:

Re: NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This notification is filed by Prometheon Labs LLC, 750 Lexington Avenue, New York, NY 10022 pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 343 (r)(6).

Name of Dietary Supplement

Avatar 8™ with AC-11®

Name of Dietary Ingredient

See attached ingredient listing

Statement of Nutritional Support
for the Dietary Ingredient

- anti-inflammatory, helps prevent release of pro-inflammatory agents
- helps relieve pain due to inflammation caused by injury or chronic condition
- helps repair damaged tissue through DNA repair
- energizing yet relaxing
- helps speed recovery from injury or fatigue
- helps prevent muscle fatigue
- quick acting
- help reduce swelling and immobilization
- helps improve joint function and range of motion
- anti-oxidant, helps reduce free radical damage
- adaptogenic all natural formula

2005-656
Aims

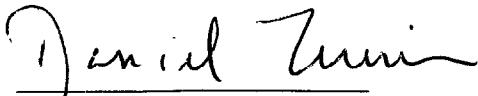
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Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS 800)
Food and Drug Administration
September 2, 2005
Page 2

Pursuant to Food and Drug Administration Regulation 21 C.F.R. § 101.93 (a)(3), a signed certification is attached to this notice.

Respectfully submitted,

Daniel Zwiren

A handwritten signature in cursive script, reading "Daniel Zwiren", written over a horizontal line.

President
Prometheon Labs LLC

Prometheon Labs LLC ~ 750 Lexington Avenue, New York, NY 10022

Prometheon Labs - Avatar 8 Supplement Facts

Actual Size

SUPPLEMENT FACTS		
Serving Size: 1 Capsule		
Servings Per Container: 60		
	Amount Per Serving	% DV
AC-11® (Patented extract of <i>Uncaria tomentosa</i> , standardized to 8% Carboxy alkyl esters)	350 mg	†
Turmeric rhizome extract (<i>Curcuma longa</i> , 20% curcuminoids)	35 mg	†
Bromelain (2,240 GDU/g)	25 mg	†
Atractylodes rhizome extract (<i>Atractylodes macrocephala</i> , 1% atractylones)	20 mg	†
L-Theanine	20 mg	†
Ginger root extract (<i>Zingiber officinale</i> , 5% gingerols)	15 mg	†
Rhodiola root powdered extract (<i>Rhodiola rosea</i> , 3% rosavins)	15 mg	†
Alpha-Lipoic acid	10 mg	†
Green tea leaf standardized extract (<i>Camellia sinensis</i> , 98% polyphenols)	5 mg	†
† DV (daily value) not established		
Other ingredients: vegetarian capsule (cellulose), dicalcium phosphate, magnesium stearate, and silica.		

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PROMETHEON LABS LLC

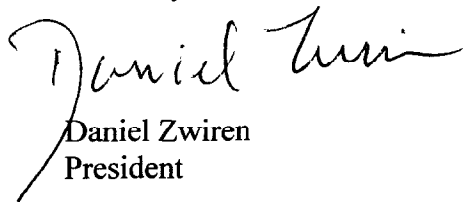
September 2, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS 800)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

To Whom It May Concern:

I certify that the information contained in the enclosed notification, filed by Prometheon Labs LLC is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel Zwiren". The signature is fluid and cursive, with the first name "Daniel" being more prominent and the last name "Zwiren" written in a more compact, cursive style.

Daniel Zwiren
President